DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
M32Ader

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

December 7, 1999

WARNING LETTER
CHI-4-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Steven Dimas, Vice President, Operations
Stat Home Care Inc.
310 Gerri Lane
Addison, IL 60101

Dear Mr. Dimas:

During a recent inspection of your oxygen repackaging facility, Investigator Lisa Hornback documented significant deviations from Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). These deviations cause your firm's Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

These deviations included:

1. Failure of the Quality Control Unit to review and approve all drug product production and control records, including those for packaging and labeling, to determine compliance with all established, approved procedures before a batch is released and distributed [21 CFR 211.192]. The instant inspection revealed that no quality review or approval of production records for liquid Oxygen, USP, is performed by your firm.

2. Failure to calibrate instruments, apparatus, gauges and recording devices at suitable intervals in accordance with the manufacturer's instruction manual [21 CFR 211.160(b)(4) & 21 211.194(d)]. For example, the inspection revealed that no records are maintained which document that the [redacted], which is used to conduct identity testing of liquid oxygen, is calibrated every eight hours as required by the instruction manual.

3. Failure to establish adequate written procedures for production and process controls covering all aspects of your firm's operations designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess [21 CFR 211.100(a)]. For example, there are no procedures which address the examination and testing of home cryogenic units that have been repaired by an outside facility.

4. Failure to establish and follow written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products [21 CFR 211.130]. For example, the inspection revealed that your firm does not apply any labels to the cryogenic vessels that your firm transfills with liquid Oxygen, USP.

This letter is not intended as an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

We acknowledge the fact that on November 11, 1999, you informed investigator Hornback that your firm has visited [redacted] customers in the Chicago area and applied required labeling to each of the cryogenic vessels and we commend you for that action.

You should take prompt action to prevent a repeat of these deviations. Failure to prevent the deviations may result in regulatory action being initialed by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

You should notify this office in writing, within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your written response should be directed to the attention of George F. Bailey, Compliance Officer.

Sincerely,

\s\
Raymond V. Mlecko
District Director